510(k) SUMMARY

SEP 23 2010

A. Submitter's Information:

Name:	Thomas Medical Products – A GE Healthcare Company
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.651.5000
Facsimile:	610.651.5003
Contact Person:	Tim Stoudt
Title:	Manager, QA / RA
Date Submission Prepared:	February 26, 2010

B. Device Information:

Trade name:	ScoutPro Inner Catheters
Classification Name(s):	Percutaneous Catheter (21 CFR §870.1250)
Common or usual name(s):	Guide catheters and accessories

C. Legally marketed device to which equivalence is claimed:

Guidant Corporation Rapido™ Guiding Catheter (K021455)
and
Merit Medical Systems, Inc. Impress Radiology Catheter (K053171)

D. Description of the device:

The Thomas Medical Products, Inc. (TMP) ScoutPro Inner Catheters are intended to access the coronary venous system, either alone or in a telescopic assembly with other introducers. The guide catheters serve as a conduit to guide devices, including guidewires, or to deliver contrast medium into specific branches of the coronary venous system. ScoutPro Inner Catheters are not intended to introduce left ventricular leads through their lumen. They have direct contact to the inner heart. ScoutPro Inner Catheters come with a 50° to 90° tip angle. They are designed as single use devices and for short term application (< 24 hours). Only medical doctors and medical personnel, who are well trained in cardiology, should apply these catheters.

The ScoutPro Inner Catheters are designed for guiding devices, including guidewires, with an outer diameter smaller than 1.1 mm. In addition, the ScoutPro Inner Catheters can work with outer catheters. The ScoutPro Inner Catheters are compatible with the following devices:

- ScoutPro Guidewire ⌀ 0.035" (BIOTRONIK #359805)
- ScoutPro hemostatic valve (BIOTRONIK #345779)
- Various ScoutPro 7F catheter shapes (Extended Hook Right BIOTRONIK#35937, Extended Hook #350369, Straight #359371, MPEP #359373, BIO2 #359374, Amplatz 6.0 #350235, Hook #350236, Multipurpose Hook #350237, Extended Hook Right L #361531, Extended Hook L 3361530, Straight L #361536, MPEP L #361533, BIO2 L #361529, Amplatz 6.0 L #361527, Hook L #361532, Multipurpose Hook L #361534)
- Commercially available Guide Wires (0.014" – 0.035")
- Commercially available medical devices with male Luer-Lock (stopcocks, syringes)
- Commercially available fluid x-ray diagnostic contrast media.

The ScoutPro Inner Catheters have a shaft design with four (4) gradually decreasing stiffness segmentations from proximal to distal. The shaft is reinforced by a metal braid from the proximal end until approximately 32 mm from the distal end. The shaft is coated by a medical-grade coating that provides enhanced lubricity when advanced through an outer catheter or in the coronary vasculature.

The proximal end is equipped with a hub that has a female luer lock connector for adapting a syringe or a three way stopcock with luer lock connections..

There are differing versions in the curve form, 50° to 90° curve at the distal end, that is used according to the anatomy of the present coronary vasculature. The distal soft tip has a tapered outer diameter and the distal tip further contains a platinum/iridium marker ring for enhanced x-ray visibility.

Package contents:
- One (1) guide catheter
- One (1) 3-way stopcock
- One (1) Instructions for use manual.

E. Intended use of the device:

ScoutPro Inner Catheters are indicated for the delivery of contrast media or Biotronik devices into the left ventricular coronary venous system. ScoutPro Inner Catheters are not intended to introduce left ventricular leads through their lumen.

F. Summary of the technological characteristics of the device compared to the predicate devices:

Features	ScoutPro Inner Catheters	Guidant Rapido Guiding Catheter K021455	Merit Impress Radiology Catheter K053171
Hemostasis valve provided	No	No	No
Compatible with .038" guide wire	Yes	Yes	Yes
Introducer available in 65cm length	Yes	No	Yes
Introducer set available in 7F	Yes	No	No
Multi-durometer catheter shaft	Yes	Yes	Yes
Teflon inner liner	Yes	Yes	Yes
Wire reinforcement completely encapsulated	Yes	Yes	Yes
Radiopaque tip or marker	Yes	Yes	Yes
Luer lock hub	Yes	Yes	Yes

G. Testing:

	Test Description	Results
Simulated Use Testing		
ScoutPro Inner Catheter		
	insertion and removal forces of .014" and .035" guidewires	Pass
	insertion and removal forces through outer sheath and valve	Pass
	shaft kink and buckling resistance	Pass
	tip section kink, corrugation, and peel back resistance	Pass
	curve configuration after straightening	Pass
	shaft joint integrity when bend around mandrel	Pass

	Test Description	Results
Physical/Dimensional Testing		
Stopcock		
	leak resistance of stopcock/catheter assembly	Pass
ScoutPro Inner Catheter		
	pull forces of shaft joints	Pass
	pull force of hub/tube joint	Pass
	tube shaft O.D.	Pass
	tip section O.D.	Pass
	tip I.D.	Pass
	length	Pass
	curve configuration	Pass

H. Substantial equivalence rationale:

The ScoutPro Inner Catheters substantially equivalent to the currently marketed predicate devices. This assessment is based upon analysis of similar technological characteristics, bench testing, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Thomas Medical Products
c/o Mr. Tim Stoudt
Manager, QA/RA
65 Great Valley Parkway
Malvern, PA 19355

SEP 23 2010

Re: K101015
ScoutPro Inner Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 8, 2010
Received: September 9, 2010

Dear Mr. Stoudt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

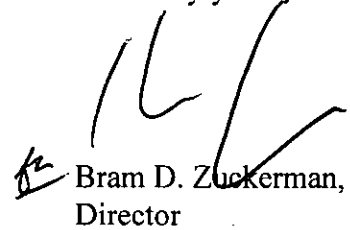
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101015

510(k) Number (if known): K101015

Device Name: ScoutPro Inner Catheters

SEP 23 2010

Indications For Use:

ScoutPro Inner Catheters are indicated for the delivery of contrast media or Biotronik devices into the left ventricular coronary venous system.

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use _____ (Per 21 CFR 801 Subpart C)

(Optional Format 11-13-03)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101015

510(k) "Indications For Use" Form (Replica of FDA Form)